

**Amendments to the Drawings:**

The attached sheet of drawings includes changes to Fig. 4. This sheet, which also includes Figs. 3 and 6, replaces the original sheet including Figs. 3, 4 and 6. In Fig. 4, the previously omitted reference numeral "34" has been added.

Attachment: Replacement Sheet  
Annotated Sheet Showing Changes

**REMARKS**

This paper is responsive to the final Office Action dated June 9, 2009. In the Office Action, all claims 1, 3, 5-22, 25-29 and 32 were rejected. No claim amendments are presented in this paper. For the following reasons, reconsideration of the rejections is requested.

**Claims 1, 3, 5-7, 9.**

Claims 1, 3, 5-7 and 9 were rejected under 35 USC §103(a) as being unpatentable over Cox (USP 4,340,046) in view of Stuart (USP 5,778,877).

Claim 1 is directed to a tracheostomy tube comprising a hollow tubular body having a proximal end portion, a distal end portion and a curved portion intermediate the proximal and distal end portions. The hollow tubular body includes a collar at its proximal end, the collar having a groove. A flange is situated at the proximal end portion of the tubular body. The flange is capable of selective attachment to the tubular body and removal therefrom. The flange extends radially from the proximal end portion when attached thereto, and includes a cut-away portion extending radially inwardly from a lateral side thereof. The cut-away portion and the groove are cooperatively sized and shaped to mate when the flange is attached to the tubular body.

According to the Examiner, Cox teaches a trach tube including a removable flange situated at a proximal portion of the tube. Stuart was said to teach a trach tube device having a collar and a groove for cooperatively engaging a flange cut-away portion. The Examiner has not identified a flange cut-away portion in either reference that extends radially inwardly from a lateral side thereof, and wherein the cut-away portion and the groove are cooperatively sized and shaped to mate when the flange is attached to the tube.

One example of the cut-away portion is designated in Fig. 4<sup>1</sup> by reference numeral 34, and is described in the specification, e.g., at paragraph [0031]. Applicants have also not been able to identify any structure in the cited references that can be considered to meet this limitation. By providing a cut-away portion that extends radially

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<sup>1</sup> Upon review, Applicant notes that the reference numeral "34", while referred to on two occasions in paragraph [0031], was inadvertently omitted from Fig. 4. A corrected figure is provided in the Appendix.

inwardly from a lateral side of the flange, the flange can easily be selectively attached and detached from the tracheostomy tube, e.g., by a snap-fit or other attachment means. This arrangement facilitates use of the removable flange by providing a rapid and convenient means for attachment and removal, even after the tracheostomy tube has been positioned along the trachea of the patient. Neither Cox nor Stuart teaches or suggests such an arrangement.

As discussed in the present specification (paragraph [0039]), when using a conventional tracheostomy tube having the flange attached thereto in well-known fashion, it is difficult, if not impossible, to withdraw an introducer sheath (most particularly, a radially expandable introducer sheath as shown in Figs. 1 and 2 of the present application), from the tracheal opening following placement of the tracheostomy tube. This is because the presence of the radially-extending flange that is attached to the tracheostomy tube increases the effective outer diameter of the tracheostomy tube/dilator combination, which increased diameter obstructs smooth withdrawal of the introducer over the tracheostomy tube. Examples of tracheostomy tubes having this increased radial diameter owing to the presence of the flange are abundant in the prior art and may be observed, e.g., in Fig. 1 of Cox and in Fig. 7e of Stuart.

By providing a flange having a cut-away portion that extends radially inwardly from a lateral side of the flange, as shown in Fig. 4 of the present specification, the flange can be easily snapped onto, and off of, the tracheostomy tube as desired. Thus, when inserting a tracheostomy tube that has not yet had the flange attached, or from which the flange has been detached in a manner such that it no longer obstructs removal of the sheath, the introducer sheath can be readily withdrawn in an axial direction over a properly positioned tracheostomy tube. Once the sheath has been withdrawn, the flange can be simply snapped or otherwise affixed to the tracheostomy tube. Neither of the cited references teaches or suggests a tracheostomy tube having this capability.

In the Office Action, the Examiner pointed out that Stuart has a collar with a groove (34, 36) for cooperatively engaging a flange cut-away portion. However, the structure in Stuart recited by the Examiner is annular with an opening in the center. It does not have a cut-away portion that extends radially inwardly from a lateral side

thereof that permits easy flange engagement or disengagement, nor does it includes an arrangement wherein the cut-away portion and a groove in the tracheostomy tube collar are cooperatively sized and shaped to mate when the flange is attached to the tubular body. As a result, the flange cannot be selectively attached and removed from the tracheostomy tube by simply sliding it onto, or off of, the tracheostomy tube. The combination cited by the Examiner would be cumbersome and difficult to use in the inventive structure, if possible at all.

In her Response to Arguments, the Examiner states that all that is required in the claims is a flange that can be removably attached to the tube, and a flange having a cut-away portion/groove. Applicants respectfully submit that the claim also specifies that the cut-away portion extends radially inwardly from a lateral side of the flange. This structure, which is not taught or suggested in the cited references, enables the flange to be simply slid onto the tube. The structure also further distinguishes the claimed tube from the cited art, which does not have this capability for easy engagement or disengagement.

Claims 5-7 and 9 depend from claim 1, and therefore include all of its limitations. Therefore, these claims are also not obvious in view of the cited combination for at least the same reasons that claim 1 is not obvious.

#### **Claims 12-21.**

Claims 12-21 were rejected under 35 USC §103(a) as being unpatentable over Cox in view of Mizus (USP 4,960,122).

Claim 12 is directed to an insertion device comprising a tracheostomy tube and a loading dilator. The tracheostomy tube has a longitudinal bore and a tapered distal tip. The loading dilator has a larger-diameter stepped proximal portion and a smaller diameter distal portion extending from the larger diameter proximal portion. The smaller diameter distal portion has a generally cylindrical profile, wherein the generally cylindrical profile tapers to a tapered distal end. The smaller-diameter distal portion is sized to be insertable through the longitudinal bore of the tracheostomy tube such that the tapered distal end extends axially beyond the tapered distal tip of the tracheostomy tube. The proximal end of the tracheostomy tube comprises a stop portion for engaging a distal

portion of the larger-diameter stepped portion of the dilator to limit axial movement of the loading dilator through the tracheostomy tube.

According to the Examiner (OA, page 4), the difference between the instant claims and Cox is that Cox lacks the cylindrical profile tapering to a tapered distal end. Mizus was said to teach a tracheostomy tube with a loading dilator having a cylindrical profile that tapers to a tapered distal end that extends beyond the end of the tube.

Applicants respectfully take issue with the Examiner's comments concerning the Cox disclosure, as well as the cited combination. Applicants point out that there is no suggestion in Cox to provide a taper to a smaller diameter portion as claimed herein. Providing the taper as claimed herein enables the physician to conveniently insert the tracheostomy tube into the trachea using the combined tracheostomy tube/loading dilator, wherein a smooth tapered distal profile results therefrom.

The Examiner cites Mizus for teaching a loading dilator that tapers to a tapered distal tip. In response, Applicants point out that Mizus teaches an obturator, not a loading dilator. As such, it is more in the nature of a "place holder", than of a structure that functions to facilitate insertion of a tracheostomy tube. The tapered end does not appear to have any functional significance in the Mizus device, as the obturator would appear to be able to perform its intended function equally as well if it did not have a tapered distal end. As a result, it is unclear to Applicants why the teaching of Mizus would even be of interest to a skilled artisan looking to modify the teaching of Cox to arrive at an insertion device having a tapered distal end, as Mizus teaches no significance of this structure. In addition, even if the obturator of Mizus can be considered in the nature of a loading dilator, Mizus does not provide any indication that the feature of a stepped large-diameter proximal portion sized for engagement with a stop portion at the proximal end of the tracheostomy tube, for limiting axial movement of the loading dilator through the tracheostomy tube would be of any interest or benefit.

If the present invention involved nothing more than simply combining a tapered dilator with a tracheostomy tube, then perhaps the cited combination would be sufficient. However, the claims at issue involve a very precise manner of combining a loading dilator with a tracheostomy tube. In this instance, features at both the proximal end (e.g., the "stop" feature and the claimed diametrical relationship) and at the distal

end (e.g., the merging of the respective tapered ends to form a profiled tapered end) interrelate in the manner discussed in the claim to provide the claimed insertion device.

Had the claimed invention merely required use of a tapered dilator, then Cox could have come up with that. However, Applicants respectfully submit that much more than that is encompassed in the claims. It is only upon the improper use of hindsight using Applicants' disclosure as a guide that the present claims can be reconstructed by picking and choosing disparate features found in these two references. Applicants submit that all of the claimed features must be considered in an obvious analysis, as well as their interrelationship in the completed device. When proper consideration of all such features is considered, it is clear that the claimed invention includes much more than the simple combination of individual features taken from multiple references as set forth by the Examiner.

Claims 13-21 depend, directly or indirectly, from independent claim 12, and therefore include all of its limitations, including the limitations referenced above related to a loading dilator having a larger-diameter stepped proximal portion and a smaller diameter distal portion, wherein the smaller diameter distal portion tapers to a tapered distal end. Thus, these claims are believed allowable over the cited combination for at least the same reasons that claim 12 is allowable.

#### **Claims 22-29.**

Claims 22-29 were rejected were rejected under 35 USC §103(a) as being unpatentable over Cox in view of Varner (USP 6,105,577).

Claim 22 is directed to a device for percutaneous insertion into the trachea of a patient. The device includes a tracheostomy tube having a longitudinal passageway therethrough. The tracheostomy tube has a distal end portion percutaneously insertable into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted. The tracheostomy tube has a radially extending flange capable of selective attachment to and removal from the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea for insertion of the tracheostomy tube. A locking assembly is provided for locking the

tracheostomy tube to the dilator during insertion of the tracheostomy tube into the trachea. The locking assembly comprises a securement member associated with the dilator, wherein the securement member is engageable with a complementary member on the tracheostomy tube. The locking assembly further comprises a stop member disposed on an outer surface of the dilator. The stop member is engaged with the dilator such that substantial axial movement of the stop member along said dilator is prevented when an axial force is applied to the stop member. The stop member is positioned on the outer surface and engageable with the securement member and the complementary member for preventing excess penetration of the tracheostomy tube into the trachea.

The Examiner acknowledged that Cox is silent as to a locking assembly for locking the trach tube to the dilator during insertion of the trach tube. Varner was cited for disclosing an inner cannula including locking means for securing the tube to the trach tube. Therefore, according to the Examiner, it would have been obvious to include the locking means of Varner in the dilator of Cox to secure the dilator to the trach tube during insertion "so that the tapered distal tip didn't actually slip axially up into the trach tube."

Applicants respectfully disagree. First, Applicants assert that an inner cannula cannot be reasonably equated to a dilator in the claimed structure described above. The present specification distinguishes these two structures, and in fact, specifically refers (at page 12, lines 5-6) to an inner cannula as a separate element from a dilator. In view of the distinction noted in the present specification, one skilled in the art would not equate features provided with an inner cannula with features on a dilator.

In addition to the foregoing, Applicants submit that the Examiner has combined two disparate references to elicit a solution to a problem that neither of the references has addressed nor even recognized. When a tracheostomy tube as described herein that does not have a neck flange attached is inserted into the trachea of a patient using an introducer sheath, it would be possible to inadvertently insert the tracheostomy tube too far into the body opening. Normally, the presence of the flange on a conventional tracheostomy tube prevents excessive penetration of the tube into the trachea. However, when using a tracheostomy tube having a removable flange as described

hereinabove, the flange will not normally have been attached to the tube at the time that the tube is introduced into the body (to permit easy removal of the introducer sheath following insertion of the tracheostomy tube). Therefore, without the presence of the flange to prevent undue penetration, the tracheostomy tube might inadvertently be inserted an excessive distance into the trachea. If this occurs, there is often no convenient way to retrieve the tube without causing additional trauma to the patient.

If the tracheostomy tube is inadvertently inserted too far when the dilator and tracheostomy tube are connected utilizing the claimed structure, the physician can retrieve the tracheostomy tube from the body by simply pulling back on the loading dilator. Once the tracheostomy tube is in proper position in the body, the securement cap can be disconnected from the tracheostomy tube. The loading dilator and the securement cap can then be removed in tandem, and the attachable flange can then be connected to the tracheostomy tube.

Applicants wonder where one skilled in the art would find any motivation to combine two references that do not even recognize the problem solved herein, and to combine the teachings of those references in a very specific way to arrive at the claimed invention. Applicants respectfully submit that basing an obviousness rejection on these references stretches the reach of Section 103(a) beyond any reasonable limits. Reconsideration is requested.

In addition to the foregoing, the Examiner has identified the gripping teeth (130) of Varner as meeting the limitation of a securement member (130) of a locking mechanism. According to claim 22, the stop member for preventing excess penetration of the tracheostomy tube into the trachea is positioned on the outer surface of the dilator and is engageable with the securement member and the complementary member. No such stop member is provided in Varner. It is unclear which structure the Examiner considered as meeting this limitation, but Applicants submit that there is no indication in Varner that any of the structure on the outer surface of the dilator (or inner cannula) is suitable for this purpose. In fact, in view of the structure of the device of Varner and the nature of the inner cannula 128, it would be surprising indeed to find a stop member as claimed herein in the Varner inner cannula, as no purpose would seem to be served by such structure on the Varner device.

Applicants submit that the locking assembly of Varner is considerably different from the securement member/stop mechanism of the present invention, is provided for different purposes, and cannot be readily transformed into the claimed structure without the exercise of inventive effort, as well as wholesale reconstruction. Nothing in Cox and/or Varner teaches or suggests to the skilled artisan a solution to the problem of excess tracheostomy tube penetration as described above. For the foregoing reasons, reconsideration is respectfully requested.

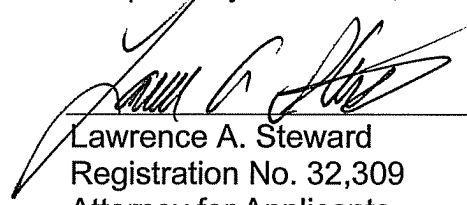
**Claims 8, 10, 11, and 32.**

Dependent claims 8, 10, 11 and 32 were rejected under 35 USC §103(a) as being unpatentable over Cox in view of at least one secondary and tertiary reference. For purposes of this response after final action, Applicants will not separately argue these rejections. Each of these claims depends on one of independent claims 1, 12, and 22, and includes all of the limitations of the respective independent claim. This, these claims are believed allowable for at least the same reasons as the respective independent claims.

**Conclusion.**

For at least the reasons provided hereinabove, Applicants respectfully submit that all claims 1, 3, 5-22, 25-29, and 32 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution may be advanced by a telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,



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